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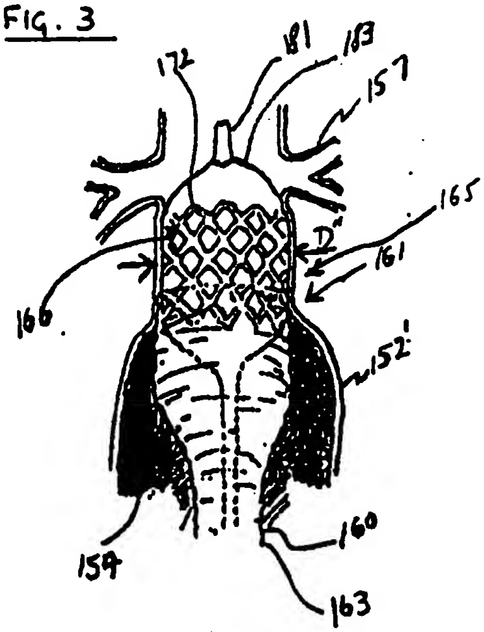
(54) **Aortic graft, and method and apparatus for repairing an abdominal aortic aneurysm.**

(57) An aortic graft (150), and method and apparatus for repairing an abdominal aortic aneurysm includes a tubular graft (160) which is intraluminally delivered through the aorta and secured to the aorta by the expansion and deformation of a thin-walled tubular member (165).

FIG. 3



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sis therein to support and reinforce the graft; is suitable for older patients with chronic illnesses; and is more readily performed on an emergency basis after rupture of the aneurysm. Therefore, the art has sought an aortic graft intraluminal delivery, and method and apparatus for repairing an abdominal aortic aneurysm which is believed to: not have a high morbidity and mortality rate; does not require an abdominal incision and general anesthesia; not require an extended recovery period; not require suturing the graft to the remaining aortic wall; permit the existing aortic wall and thrombosis therein to be retained to reinforce and support the aortic graft; be suitable for patients having other chronic illnesses; and be more readily, quickly performed on an emergency basis after rupture of the aneurysm.

In accordance with the invention, the foregoing advantages have been achieved through the present aortic graft for intraluminal delivery to repair an abdominal aortic aneurysm in an aorta having two iliac arteries associated therewith. The present invention includes a tube having first and second ends and a wall surface disposed between the two ends, at least a portion of the tube adapted to be disposed within the abdominal aortic aneurysm; means for securing the first end of the tube to the aorta, the securing means including a thin-walled tubular member having first and second ends and a smooth outer wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member; the first end of tube being secured to the second end of the tubular member; the tubular member having a first diameter which permits intraluminal delivery of the tubular member into the aorta and the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to secure the first end of the tubular member to the aorta.

A further feature of the present invention is that the second end of the tube may be bifurcated and two tubular passageways are formed which are in fluid communication with the first end of the tube and the two passageways are adapted to be mated with and disposed within the two iliac arteries. Another feature of the present invention is that the two tubular passageways may include means for securing the two tubular passageways to the two iliac arteries, and the securing means may be a thin-walled tubular member which has a first diameter which permits intraluminal delivery of the tubular member into the aorta, the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to secure the tubular member to the iliac artery. A further feature of the present invention is that the first end of the tube which may be secured to the second end of the tubular member is radially expandable, whereby the first end of the tube may conform with the second expanded and deformed diameter of the second end of the tubular member. An additional feature of the present invention is that the tube may have an intermediate portion which is not substantially radially expandable. Another feature of the present invention is that the tube may be bioerodable, and it may be impervious to the flow of fluid through the wall surface of the tube.

In accordance with the invention, the foregoing advantages have also been achieved through the present apparatus for repairing an abdominal aortic aneurysm. The apparatus of the present invention includes: a tube having first and second ends and a wall surface disposed between the two ends; an expandable and deformable, thin-walled tubular member having first and second ends and a smooth outer wall surface disposed between the first and second ends, the first end of the tube being secured to the second of the tubular member, and the expansion and deformation of the thin-walled tubular member being controllable; and a catheter having an expandable, inflatable portion associated therewith, the thin-walled tubular member being releasably mounted upon the inflatable portion of the catheter, whereby upon inflation of the expandable, inflatable portion of the catheter, the thin-walled tubular member is forced radially outwardly into contact with the aorta to remain secured thereto, whereby the tube, secured to the thin-walled tubular member, provides a passageway through the abdominal aortic aneurysm.

In accordance with the invention, the foregoing advantages have also been achieved through the present method for repairing an abdominal aortic aneurysm in an aorta having two iliac arteries. The method of the present invention comprises the steps of: connecting a tube to an expandable and deformable, tubular member; disposing the tube and tubular member upon a catheter having an expandable, inflatable portion with the tubular member disposed upon the expandable, inflatable portion; intraluminally delivering the tube, tubular member and catheter to the aorta and disposing at least a portion of the tube within the abdominal

tube 160 to the aorta 152.

Preferably, securing means 165 includes a thin-walled member 166 having first and second ends 167, 168 and a smooth outer wall surface 169 disposed between the first and second ends 167, 168 of the thin-walled member 166. The thin-walled member 166 has a first diameter D' (FIG. 1), which permits intraluminal delivery of the thin-walled member 166 into the aorta 152. Upon the application from the interior of the thin-walled member 166 of a radially, outwardly extending force, as will be hereinafter described in greater detail, the thin-walled member 166 has a second, expanded and deformed diameter D" (FIGS. 3 and 4), whereby the thin-walled member 166 is expanded and deformed to secure the first end 167 of the thin-walled member 166 and the first end 161 of the tube 160 to the aorta 152. The second diameter D", as will be hereinafter described in greater detail, is variable and dependent upon the amount of force applied to the thin-walled member 166. The first end 161 of tube 160 is connected to the second end 168 of the thin-walled member 166, as by a plurality of sutures 170 (FIG. 2). Sutures 170 may be conventional sutures of polypropylene, DACRON®, or any other suitable material. Preferably, the first end 161 of tube 160 overlaps and covers the second end 168 of thin-walled member 166, such overlap being approximately 50% of the length of thin-walled member 166. The first end 161 of tube 160, which overlaps the second end 168 of thin-walled member 166, is preferably constructed so that it is radially expandable, whereby the first end 161 of tube 160 may conform with the second, expanded and deformed diameter D" of the second end 168 of the thin-walled member 166 as seen in FIGS. 3 and 4. If tube 160 is woven, the weave of the material at its first end 161 is looser, so that the desired radial expansion can be obtained. The intermediate portion 171 of tube 160 disposed between first and second ends 161, 162 thereof, is preferably not substantially radially expandable.

Still with reference to FIGS. 1-4, thin-walled member 166 is preferably a thin-walled tubular member 172 whose wall surface 169 has a substantially uniform thickness with a plurality of slots 173 (FIGS. 1 and 5) formed therein, the slots 173 being disposed substantially parallel to the longitudinal axis of the tubular member 172. It has been found that one type of thin-walled member 166, or tubular member 172, which is particularly useful as securing means 165 are the expandable intraluminal grafts disclosed in U.S. Patent No. 4,733,665, issued March 29, 1988; U.S. Patent No. 4,739,762, issued April 26, 1988; and U.S. Patent No. 4,776,337, issued October 11, 1988, all the foregoing patents being in the name of Julio C. Palmaz, and assigned to Expandable Grafts Partnership. Each of these patents is incorporated herein by reference. Other thin-walled members 166, or tubular members 172 could be utilized as securing means 165, provided they have ability to be controllably expanded and deformed from the first diameter D', which permits intraluminal delivery of securing means 165, to the second expanded and deformed diameter D", in order to secure the thin-walled member 166, and connected tube 160 within aorta 152.

Still with reference to FIGS. 1-4, tube 160, preferably has a generally, circular cross-sectional configuration, and tube 160 may be made from a variety of materials, provided they have the requisite strength characteristics to be utilized as an aortic graft 150, as well as have the requisite compatibility with the human body in order to be used as a graft, or implant material, without being rejected by the patient's body. Examples of such materials are DACRON® and other polyester materials, TEFLON® (polytetrafluoroethylene), TEFLON® coated DACRON® material and porous polyurethane. The material can be knitted or woven, and can be warp or weft knitted. If the material is warp knitted, it may be provided with a velour, or towel like surface, which speeds up clotting of blood which contacts tube 160 in order to increase the attachment, or integration, of tube 160 to aorta 152, or to assist the integration of tube 160 to the thrombosis 154. Tube 160 can also be made of a bio-erodable, or degradable material, such as albumin or collagen or a collagen coated material. A tube 160 which is bio-erodable, would erode and dissolve, or degrade, over a period of time; however, it is believed that a layer of endothelium, or skin, will grow as the tube 160 erodes, the new layer of endothelium, or skin, providing a new, fluid impervious lining within aneurysm 151. As will be hereinafter described in greater detail, when aortic graft 150 is utilized in connection with an emergency insertion after a rupture of aneurysm 151, it would be preferable to make tube 160 of a fluid impervious material. Additionally, the tube 160 or securing means 160 could have a coating of a biologically innert material, such as TEFLON® or porous polyurethane.

Still with reference to FIGS. 1-4 tube 160 may have a crimped configuration to form an undulating longitudinal cross-sectional configuration (FIG. 1), whereby kinking, or twisting, or folding over upon itself will be minimized when the tube 160 is secured within the aneurysm 151, as will be hereinafter described in greater detail. This undulating configuration can be obtained by heat stamping tube 160, or in any other suitable manner, whereby the tube 160 has a "memory" and if it is twisted or kinked, it will return to its original

connector members 196 are utilized, the connector members being disposed 180° apart, whereby the surgeon can determine by x-ray or fluoroscopy that the two flexible connector members 196 are disposed in the position shown in FIG. 7, wherein the second connector member (not shown) is disposed directly behind the first connector member 196. If two images of connector members 196 appear on the x-ray or the fluoroscope, the surgeon will know that it is possible that one of the renal arteries 157 may be obstructed by one of the connector members 196. Securing means 165' is expanded and deformed in the same manner as previously described with respect to securing means 165.

With reference to FIG. 8, a graft 150''' is illustrated, graft 150''' being similar in design to the graft 150 illustrated in FIG. 4, with the exception that the second end 162 of tube 160 is provided with additional securing means 192 as previously described in connection with FIG. 7.

With reference to FIGS. 9-12, a method for repairing an abdominal aortic aneurysm 151 and iliac aneurysm 190 with an aortic graft 150' as illustrated in FIG. 6 will be described. After tube 160 has been connected to an expandable and deformable thin-walled member 166, or tubular member 172, as previously described in connection with FIGS. 1-5, a surgical wire 200 is introduced through a conventional catheter insertion device 201 through the right femoral artery 202R. In a conventional manner, the surgical wire 200 is passed from the right femoral artery 202R upwardly through the right iliac artery 153R through the aorta 152 and downwardly through the left iliac artery 153L and into the left femoral artery 202L and into another conventional catheter insertion device 201. Apparatus 180, including tube 160, catheter 181, and thin-walled member 166 are then intraluminally delivered into the aorta 152 and aneurysm 151, through the left femoral artery 202L, via a conventional catheter insertion device 201. Securing means 165 can be disposed in the aorta 152 in the position shown in FIGS. 9 and 1. Sheath 186 may then be removed in a conventional manner. With reference to FIGS. 10 and 11, after sheath 186 is removed, surgical wire 200 may then be sutured to the right passageway 191R of tube 160 as shown in FIG. 10. Securing means 165 may then be expanded and deformed in the manner previously described, as shown in FIG. 11. The wire 200 can then be withdrawn and pulled, so as to pull the right passageway 191R of tube 160 downwardly into the right iliac artery 153R until it assumes the position shown in FIG. 12. This same method could also be utilized to repair an aneurysm 151, including an iliac aneurysm 191 with the graft 150'' of FIG. 7.

With reference to FIGS. 13, 13a, and 14, a method and apparatus for repairing an abdominal aortic aneurysm 151 which has ruptured as shown at 250 in FIGS. 13 and 13a is illustrated. As seen in FIG. 13a, blood is illustrated by arrows 251 as flowing through the opening, or rupture, 250 in the wall 252 of aorta 152, and the thrombosis 154 is separated from wall 252. Apparatus 180', as shown in FIG. 14, is similar to apparatus 180 previously described in connection with FIG. 5. Apparatus 180' includes tube 160 of the type as previously described, a catheter 181' having an extended nosepiece 184', tube 160 being disposed about the extended nosepiece 184'. Securing means 165, as previously described, is mounted upon an expandable, inflatable portion 183 of catheter 181'. Apparatus 180' differs from that previously described, in that catheter 181' first passes through securing means 165 and then into tube 160, whereas in apparatus 180, catheter 181 first passes through tube 160 and then into securing means 165. Sheath 186 is also provided as previously described. Additionally, the second end 162 of tube 160 is restrained in the position shown in FIG. 14, as by a thread which passes through the lower end 162 of tube 160, the thread 260 passing through the extended catheter nosepiece 184'. As will hereinafter be described in greater detail, it is preferable that thread 260 be able to be easily pulled through tube 160. Accordingly, it is preferred that thread 260 have a smooth, slippery surface. Nylon monofilament is thus a preferred material for thread 260.

As seen in FIG. 13, apparatus 180' is intraluminally delivered to the aorta and the ruptured aneurysm 151 through an axillary artery 261 in the patient's arm 262 whereby apparatus 180' is intraluminally delivered via the axillary artery downwardly through the aorta 152 into the position illustrated in FIGS. 13 and 1. Securing means 165 is then expanded and deformed in the manner previously described, so that aortic graft 150 assumes the configuration illustrated in FIGS. 4 and 13. Thread 260 is then pulled and removed from tube 160 by pulling it out through nosepiece 184'. In the event of a rupture 250, it is believed it would be difficult to enter the aorta 152 from the femoral artery, where as it is believed it will be readily possibly to intraluminally deliver apparatus 180' through the axillary artery 261 via usage of a conventional catheter insertion device 201. Because of the rapid flow of blood, it is preferred that the tube 160 be made fluid impervious when used for repairing aneurysms which have ruptured. It should be readily recognized that the procedure illustrated in connection with FIGS. 13, 13a, and 14 can be much more expeditiously performed then the conventional, prior art method for repairing a ruptured aneurysm 151.

passageways to the two illiac arteries.

10. The aortic graft of claim 1, wherein the first end of the tube is secured to the second end of the tubular member by a plurality of sutures.

11. The aortic graft of claim 1, wherein the first end of the tube which is secured to the second end of the tubular member is radially expandable, whereby the first end of the tube may conform with the second expanded and deformed diameter of the second end of the tubular member.

12. The aortic graft of claim 2, wherein the tube has an intermediate portion which is not substantially radially expandable.

13. The aortic graft of claim 1, wherein the tube is crimped to form an undulating longitudinal cross-sectional configuration, whereby kinking or twisting of the tube is minimized.

14. The aortic graft of claim 1, wherein the securing means includes first and second tubular members flexibly interconnected by at least one connector member, the first end of the tube being secured to one of the tubular members.

15. The aortic graft of claim 1, wherein the tube is bioerodable.

16. The aortic graft of claim 1, wherein the tube is impervious to the flow of fluid through the wall surface of the tube.

17. An aortic graft for intraluminal delivery to repair an abdominal aortic aneurysm in an aorta having two illiac arteries associated therewith, comprising:
(a) a tube having first and second ends and a wall surface disposed between the two ends, at least a portion of the tube adapted to be disposed within the abdominal aortic aneurysm;
(b) means for securing the first end of the tube to the aorta, the securing means including a thin-walled member having first and second ends and a smooth outer wall surface disposed between the first and second ends of the thin-walled member, the first end of the tube being connected to the second end of the thin-walled member, the thin-walled member having a first diameter which permits intraluminal delivery of the thin-walled member into the aorta, the thin-walled member having a second, expanded and deformed diameter, upon the application from the interior of the thin-walled member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the thin-walled member, whereby the thin-walled member may be expanded and deformed to secure the first end of the thin-walled member and the first end of the tube to the aorta.

18. The aortic graft of claim 17, wherein the thin-walled member has a biologically inert coating on its wall surface.

19. The aortic graft of claim 17, wherein the second end of the tube is bifurcated and two tubular passageways are formed which are in fluid communication with the first end of the tube and the two passageways are adopted to be mated with and disposed within two illiac arteries.

20. The aortic graft of claim 19, wherein the two tubular passageways include means for securing the two tubular passageways to the two illiac arteries.

21. The aortic graft of claim 20, wherein the securing means includes a thin-walled member having first and second ends and a smooth outer wall surface disposed between the first and second ends of the thin-walled member, the second end of the tube being secured to the first end of the thin-walled member, the thin-walled member having a first diameter which permits in intraluminal delivery of the thin-walled member into the aorta, the thin-walled member having a second, expanded and deformed diameter, upon the application from the interior of the thin-walled member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the thin-walled member, whereby the thin-walled member may be expanded and deformed to secure the thin-walled members and the tubular passageways to the two illiac arteries.

22. An apparatus for repairing an abdominal aortic aneurysm in an aorta having two illiac arteries associated therewith, comprising:
(a) a tube having first and second ends and a wall surface disposed between the two ends;
(b) an expandable and deformable thin-walled tubular member, having first and second ends and a smooth outer wall sur-

FIG. 1

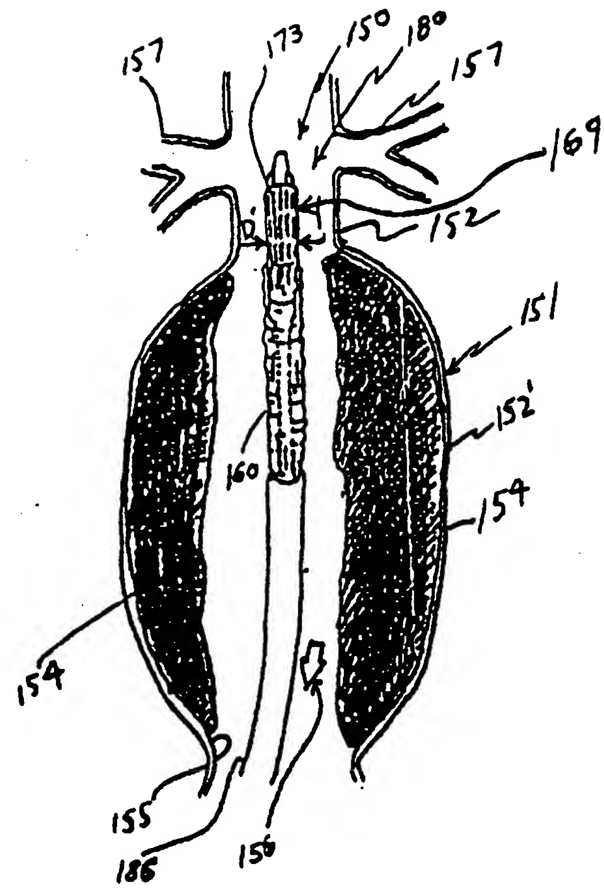

157
173
150
180
157
169
152
151
152'
160
154
154
155
186
156

FIG. 2

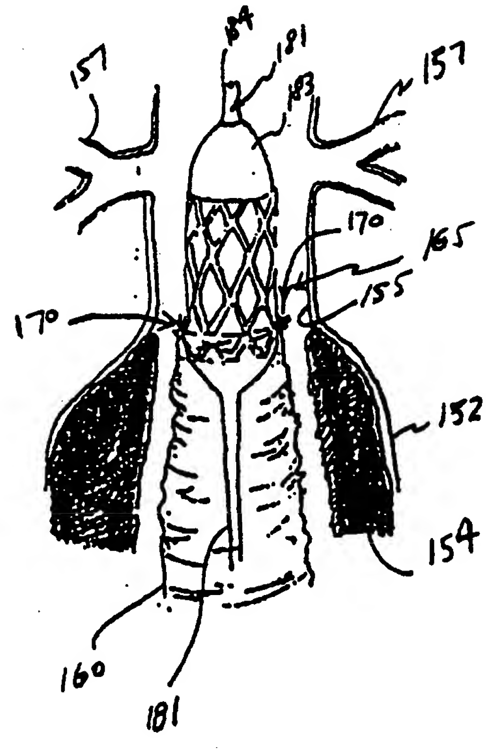

157
184
181
183
157
170
165
170
155
152'
154
160
181

FIG. 5

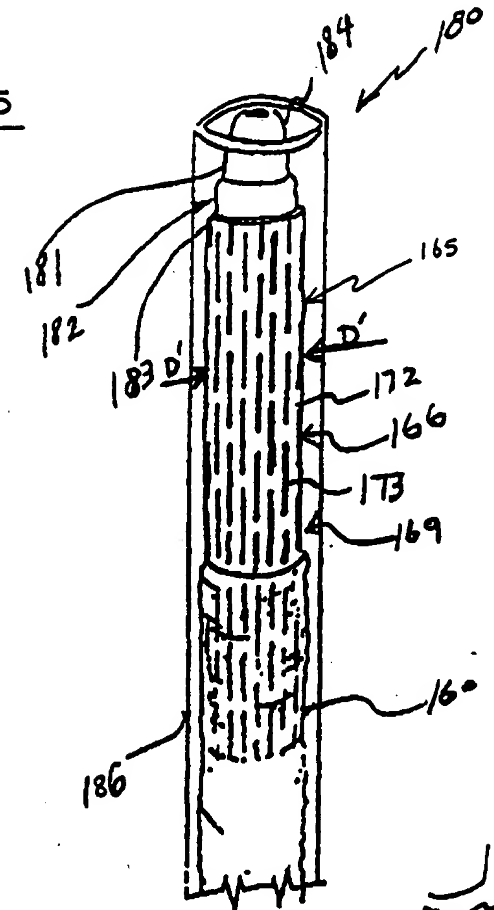

184
180
181
182
165
183
D'
D'
172
166
173
169
160
186

FIG. 6

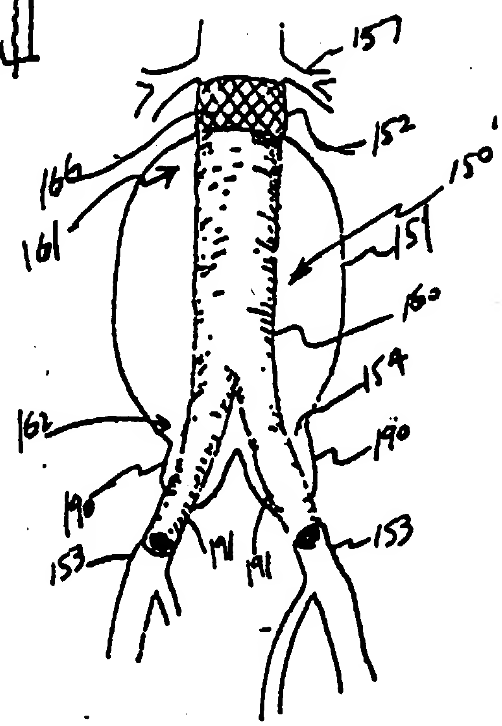

157
152
166
150'
161
151
160
154
162
190
190
153
191
191
153

FIG. 9

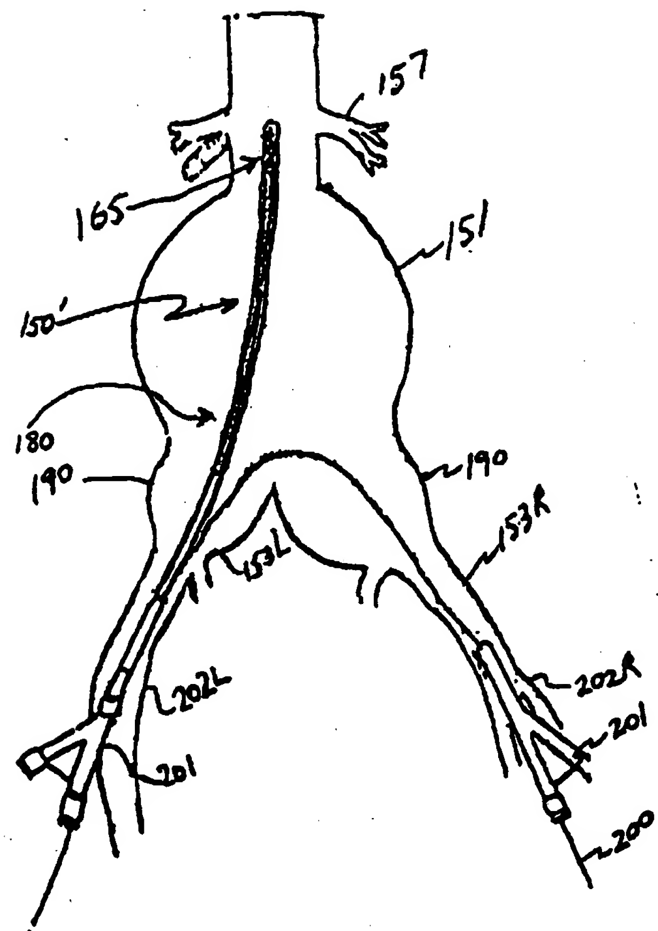


FIG. 11

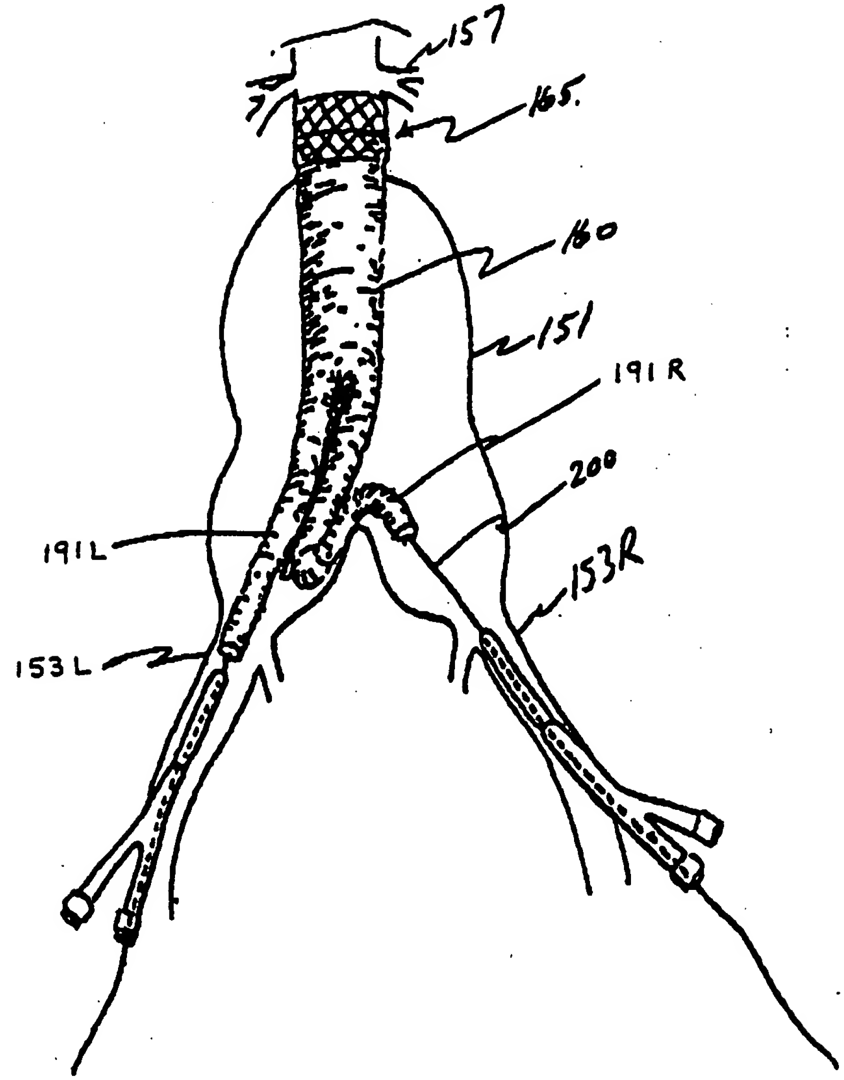


FIG. 13

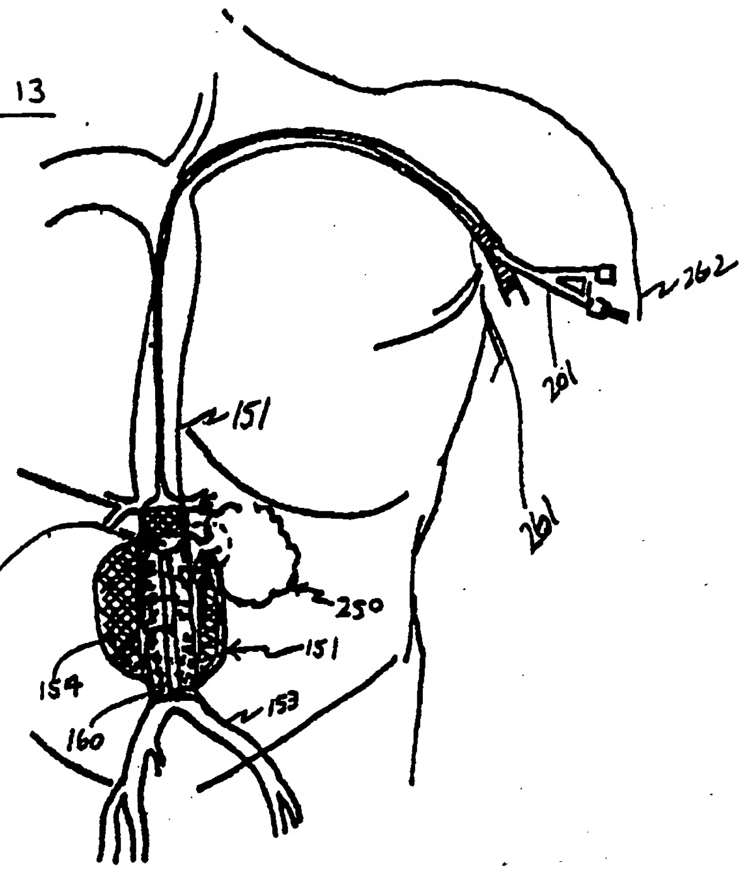
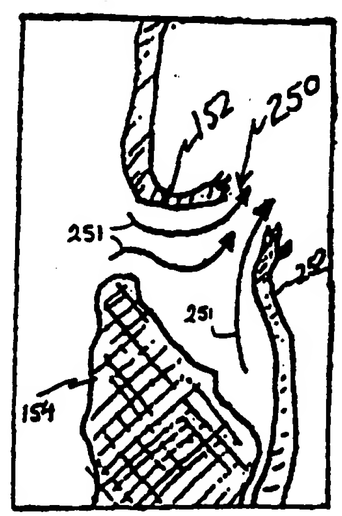


FIG. 13 a



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EUROPEAN SEARCH REPORT

Application Number

EP 91 30 4988

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
Y	US-A-3 657 744 (ERSEK) * Figure 1; column 3, lines 28-34 *	1-22	A 61 F 2/06
Y	US-A-4 562 596 (KORNBERG) * Abstract; figure 8 *	1-22	
D,A	EP-A-0 221 570 (PALMAZ) * Whole document *	1-6,9,17, 18,21	
A	US-A-4 190 909 (ABLAZA) * Column 2, lines 41-53; figure 1 *	10,16	
A	US-A-4 300 244 (BOKROS) * Column 3, lines 37-58 *	6,16,18	
A	US-A-4 787 899 (LAZARUS) * Figure 6 *	1,11,13, 18	
A	EP-A-0 334 045 (AMERICAN CYANAMID) * Example 1 *	15	
A	US-A-4 740 207 (KREAMER)		

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A 61 F

The present search report has been drawn up for all claims

Place of search	Date of completion of search	Examiner
The Hague	02 August 91	BARTON S.A.

CATEGORY OF CITED DOCUMENTS

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